PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5:		(11) International Publication Number:	WO 94/12112
A61B 17/58	A1	(43) International Publication Date:	9 June 1994 (09.06.94)

(21) International Application Number: PCT/GB93/02390

(22) International Filing Date: 19 November 1993 (19.11.93)

(30) Priority Data: 9224573.7 21 November 1992 (21.11.92) G

(71)(72) Applicant and Inventor: KLINGE, Erwin, Ludwig [GB/GB]; Hamilfield House, Beith, Ayrshire KA15 2JQ (GB).

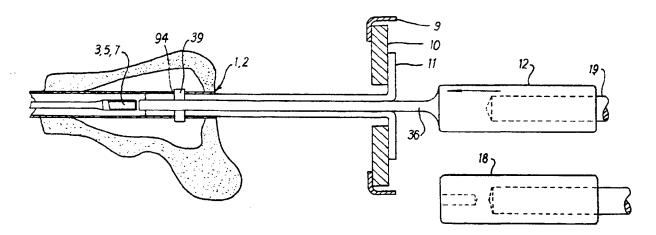
(74) Agent: PACITTI, Pierpaolo, A., M., E.; Murgitroyd and Company, 373 Scotland Street, Glasgow G5 8OA (GB).

(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

(54) Title: EXPANDING INTRAMEDULLARY NAIL



(57) Abstract

An intramedullary nail (1) is expandable along its entire length enabling it to be inserted inside a broken bone in its non-expanded form and then expanded so as to secure the bone. Such insertion can be performed without drilling into the bone and the securing of a bone using such a nail alleviates the need for subsidiary pins or nails, thus reducing operation time. Such a nail may consist of a hollow tube with broken cross section which may be expanded by forcing an insert into the break in cross section thus prising it apart.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MIR	Mauritania
ΑU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic	SD	Sudan
CG	Congo		of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MID	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	MIL	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Vict Nam
GA	Gabon				

1 Expanding Intramedullary Nail 2 3 The present invention relates to an expanding 4 intramedullary nail for uniting bone fragments and to 5 apparatus for operating the nail. 6 7 Conventionally, nails and fixing pins for bone fractures require the bone to be drilled out before the 8 9 nail or pin can be inserted. This results in loss of 10 tissues which are important for bone growth and healing 11 and can result in fat embolism while drilling. 12 devices comprise hollow sleeves accommodating 13 mechanisms, typically for extending flukes to anchor 14 the pin on the inside of the bone. 15 16 One of the disadvantages encountered with known devices 17 is that once the nail or pin is in situ it cannot easily be removed; this can cause serious problems if a 18 19 nail or pin becomes stuck before reaching its final 20 position. Such nails may also need holding in place by 21 other nails, necessitating long operations and 22 sometimes additional operations specifically to insert 23 or remove the subsidiary nails. 24 25 According to the present invention there is provided

apparatus for pinning one or more bone elements 1 comprising an intramedullary nail which is selectively 2 cross-sectionally expandable along substantially its 3 entire length, an expander for said nail and operating 4 means for operating said nail in conjunction with said 5 expander. 6 7 8 Preferably, the nail is elongate and hollow. 9 Preferably, the nail is expandable in situ within a 10 11 bone. 12 Preferably, the nail has a broken cross section along 13 substantially its entire length and is expandable by 14 15 enlarging the break in the cross section. 16 17 The nail may be configured so as to be enlargeable by 18 an expander in the form of an elongate insert, inserted into the hollow portion of the nail, where said insert 19 20 comprises a plurality of elongate members having adjacent cooperating surfaces and configured such that 21 relative axial movement of the elongate members results 22 23 in their non cooperating surfaces being forced away 24 from each other producing an increase in the total 25 effective cross section of the insert. 26 27 Alternatively, the break in the cross section may be configured so as to accommodate the insertion of an 28 expander or a selected one of a plurality of expanders, 29 each expander being in the form of an elongate member, 30 31 insertion of said expander prising open the break in the cross section by an amount determined by the size 32 33 and shape of the expander and each expander having a portion configured so as to be engageable by an 34

expander insertion and/or extraction means.

WO 94/12112

PCT/GB93/02390

	3
1	Preferably, the elongate expander has a shaped portion
2	configured to engage a portion of the inside surface of
3	the intramedullary nail configured to have a
4	complementary shape.
5	
6	Preferably, there is provided apparatus for expansion
7	and/or reversing said expansion, of the nail comprising
8	engaging means which engage the nail and means for
9	applying or releasing a force to or from said nail.
10	
11	Preferably, said apparatus is for insertion and/or
12	extraction of an expander comprising a push and/or pull
13	member which engages the expander, a forcing means
14	which provides force to the push and/or pull member and

The forcing means may comprise a screw jack mechanism, ratchet mechanism or other substantially non-percussive mechanism.

nail engaging means which helps reduce movement of the

nail relative to said apparatus.

Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings in which:

Fig 1a is a cross-section of an embodiment of an expanding intramedullary nail and a portion of an apparatus for insertion of an expander insert in accordance with the present invention;

Fig 1b is a cross-section of an embodiment of an expanding intramedullary nail and a portion of an apparatus for withdrawal of the expander insert in accordance with the present invention;

1	Fig 2a and Fig 2b are cross-sections corresponding
2	to Figs 1a and 1b of an alternative embodiment;
3	
4	Figs 3a-3f are cross-sections of the expanding
5	intramedullary nail of Fig 1 and expander insert
6	in accordance with the present invention;
7	
8	Figs 4a-4e are cross-sections of an embodiment of
9	an intramedullary nail and expander inserts,
10	alternative to those shown in fig 3a-3f. Fig 4f
11	is a further embodiment of an intramedullary nail;
12	
13	Fig 5a and Fig 5b are side views of an apparatus
14	for operation of an expanding intramedullary nail
15	in accordance with the present invention; the
16	apparatus of Fig 5a is for insertion and the
17	apparatus of Fig 5b for withdrawal of an expander
18	insert;
19	
20	Figs 6a, 6b, 7a, 7b, 8a and 8b are side and
21	frontal views showing alternative embodiments of
22	apparatus for operation of an expanding
23	intramedullary nail, in accordance with the
24	present invention;
25	
26	Figs 9a, b and c are a broken side view, end view
27	and top view respectively of an intramedullary
28	nail in accordance with the present invention;
29	
30	Figs 10a and b are side and end views of an
31	alternative embodiment of an intramedullary nail
32	in accordance with the present invention;
33	
34	Figs 11a, b and c, are side, end and top views
35	respectively of an expander of the apparatus of

1	Fig 1a, 1b, 2a or 2b;
2	
3	Figs 12a and 12b show side and end views,
4	respectively of an expander of the type
5	illustrated in Figs 4a-4e;
6	
7	Figs 13a and 13b show an alternative form of
8	expander insert;
9	
10	Fig 14 shows a preferred embodiment of apparatus
11	similar to the apparatus of Figs 6a,b;
12	
13	Figs 15a, b show a push member for use with the
14	apparatus of Fig 14;
15	
16	Figs 16a,b show a pull member for use with the
17	apparatus of Fig 14; and
18	
19	Fig 17 shows a cross section of an intramedullary
20	nail which incorporates a locking mechanism and
21	could be used with the expander of Figs 13a,b.
22	
23	Referring to the drawings a first embodiment or
24	embodiments of the present invention shall be presented
25	with reference to Figs 1a, b, 2a, b, 3a-f, 5a,b, 9a-c,
26	and 11a-c. Thereafter further alternative embodiments
27	shall be described with reference to Figs 4a-f, 6a,b,
28	7a,b, 10a,b 7a,b, 12a,b, 13a,b, 14 and 15a,b.
29	
30	The first embodiment of the present invention comprises
31	an expandable nail 1 in the form of an elongate tube
32	having a longitudinal slit 30 in the tube wall 31. The
33	expandable nail 1 has a number of expander inserts 3,
34	5, 7 to give a range of degrees of expansion. Each
35	expander insert 3, 5, 7 is formed of an elongate member

6

40 with a screw-threaded attachment end member 41. 1 elongate member 40 is of generally rectangular cross-2 section 42 with each expander insert 3, 5, 7 having a 3 different width of a first portion 37 of the 4 rectangular cross-section 42, which portion 37 5 corresponds when in situ, with the longitudinal slit 30 6 7 of the expandable nail 1 (Fig 8c). Six expander 8 inserts 3, 5, 7 are illustrated in Fig 3a to 3f with variable widths of first portion 37 of the rectangular 9 10 cross-section 42, the widths of the first portion 37 11 vary from 1 to 3.5 mm. 12 An expander insertion device 32 has a push rod 12, two 13 14 draw bars 11, a thrust plate 9, 13 or 14 and a 15 modification to the thrust plate 10. The push rod 12 16 has a thin elongate member 36 a first end of which is 17 attachable to the end member 41 of the expander insert 3, 5 or 7, while a second end of the push rod 12 has an 18 attachment sleeve 16 for attachment of a push rod 19 20 extension 22. 21 22 The insertion device 32 has a sprung ratchet tool 34, 23 attached to an end plate 21 orthogonally situated 24 around the push rod extension 22. The ratchet tool 34 25 is manually operable by means of a handle 38. 26 plate 21 is connected to the thrust plate 9 by two tie 27 rods 20, 23 which are disposed on either side of the 28 push rod 12 and push rod extension 22. The thrust 29 plate 9 and end plate 21 have centrally disposed

apertures through which the push rod 12 and push rod

placed against the end plate 21 and pushes the push rod

The ratchet tool 34 is

12 linearly along the longitudinal axis of the push rod 12 towards the expandable nail 1.

extension 22 are situated.

30

3132

1 The draw bars 11 comprise elongate members each having 2 a first end with a transverse pin 39 for location of the draw bar 11 in a fixed position to the expandable nail 1. The pin 39 is situated a short distance from 4 5 the first end of the draw bar 11 and attached to the proximal end of the expandable nail 1 by engaging a 6 7 hole 94 in said nail 1. Figs 3a to 3f show a cross-8 section of the pins 39 of the draw bars 11 and the 9 expandable nail 1. The draw bars 11 and pins 39 are 10 locked into place with respect to the nail 1 by 11 insertion of the push rod 12, 36 between the two draw 12 bars 11.

13

14 A short distance from the second ends of the two draw 15 bars 11, the elongate members bend through 90°. 16 orthogonal portions of the elongate members project 17 from the longitudinal axis of the push rod 12. The 18 thrust plate 9 and modification 10 are disposed around 19 the draw bars 11 and the push rod 12 such that the 20 orthogonal portions of the draw bars 11 are adjacent to the thrust plate modification 10 on the opposite side 21 22 of the thrust plate 9 to the expanding intramedullary 23 nail.

24

25 An expander extraction device has a pull rod 15 which 26 is attachable to the end of the expander insert 41 27 within the expandable tube 1. The pull rod 15 has a 28 diameter such that it fits closely within the 29 expandable nail 1. Two pull rods 15, 24 may be 30 connected by means of a screw threaded sleeve 16. 31 withdrawal thrust plate 13, 14 is positioned against 32 the proximal end of the expandable nail 1 and the 33 thrust plate 13, 14 has a central opening through which the pull rod 15, 24 is positioned. The sleeve 16 is 34 35 positioned on the opposite side of the thrust plate 13,

14 to the expandable nail 1. 1 2 The expander extraction device 33 has a sprung ratchet 3 4 tool 35 attached to an end plate 25 situated 5 orthogonally around the pull rod 15, 24. The end plate 25 and thrust plate 13, 14 are connected by two tie 6 7 rods 20, 23 which are disposed on either side of the pull rod 15, 24. The end plate 25 and thrust plate 13, 8 14 have centrally disposed apertures through which the 9 10 pull rod 15. 24 is situated. The ratchet tool 35 is adjacent to the end plate 25 and pulls the pull rod 15, 11 24 linearly along the longitudinal axis of the pull rod 12 13 15, 24 away from the expandable nail 1. 14 15 In use, the expanding intramedullary nail in its 16 unexpanded form is positioned in its desired position 17 inside a bone along the axis of the bone thereby 18 joining any fracture in the bone. 19 20 The expandable nail 1 is between 8 and 12 mm in 21 diameter depending on the dimensions of the bone and 22 approximately 320 mm long with a minimum wall thickness 23 of 0.5 to 1.0 mm. Intramedullary nails in accordance 24 with the present invention may be of any of a variety 25 of sizes according to the dimensions of the bone. 26 27 The expander insert 3, 5, 7 is inserted into the expandable nail 1 such that the expandable nail 1 28 29 expands along its whole length. The expander insert 3, 30 5, 7 is inserted with the first portion 37 of the 31 expander insert 3,5,7 corresponding to the longitudinal 32 slit 30 of the expandable nail 1, situated in the slit 33 The expandable nail 1 is forced to expand as the

width of the first portion 37 of the expander insert is

greater than the natural width of the slit 30 in its

34

unexpanded form. The degree of expansion of the expandable nail 1 can be controlled by choice of the appropriately sized expander insert as shown in Fig 3a to 3f.

The expander inserts 3, 5, 7 are pushed into the expandable nail 1 by use of an expander insertion The device is arranged as described above such that the action of the sprung ratchet tool 34 can be manually operated by means of a sprung handle 38. Each operation of the handle 38 pushes the push rod 12, 22 a discrete distance along the direction of the push rod's 12, 22 longitudinal axis such that it pushes the expander insert into the expandable nail 1.

The ratchet tool 34 is fixed to the end plate 21 by a weld or braze to a frame projecting from the end plate 21. The thrust plate 9 is held a fixed instance from the end plate 21 by the connecting tie bars 20, 23 between the plates 9, 21. The draw bars 11 have orthogonal portions situated on the opposite side of the thrust plate 9 to the expandable nail such that the pushing action of the ratchet tool 34 is relayed to the push rod 12 and the expander 3, 5, 7 and does not move the expandable nail 1.

When the selected expander is fully inserted into the expandable nail 1, the insertion device 32 can be removed. The expander can remain in position until such time as the expansion of the nail is to be reversed, that is, just prior to its repositioning or removal from the bone. The expander extraction device can be positioned with a pull rod 15, 24 attached to the expander insert 3, 5, 7 within the expandable nail 1. The thrust plate 13, 14 is positioned against the

1 proximal end of the expandable nail 1 and held in fixed

- 2 connection with the end plate 25 by tie rods 20, 23.
- 3 The ratchet tool 35 for withdrawal is fixed to the end
- 4 plate 25 as described for the ratchet tool 34 for
- 5 insertion. Each operation of the sprung ratchet tool
- 6 35 is manually operated by means of a sprung handle 38,
- 7 pulling the pull rod 15, 24 a discrete distance along
- 8 the longitudinal axis of the pull rod 15, 24 out of the
- 9 expandable nail 1.

10

- On withdrawal of the expander insert 3, 5, 7 the
- 12 extraction device 33 can be removed.

13

- Once the expander has been removed, the nail, being
- made from a resilient material, is allowed to revert to
- 16 approximately its unexpanded size and shape and can be
- 17 removed and used again or repositioned if necessary.
- Thus problems encountered when a nail is wrongly
- 19 positioned or obstructed before reaching its final
- 20 position are overcome.

21

- One form of expandable nail can accommodate a range of
- 23 sizes of bone and fracture although various sizes of
- 24 nail would be used according to the circumstances. No
- drilling of the bone is necessary as the insertion
- device 32 slowly pushes an expander insert 3, 5, 7 into
- 27 the expandable nail 1. The nail itself can be
- 28 positioned manually prior to expansion without drilling
- 29 because it need only be forced through relatively soft
- 30 medullary tissue.

- 32 The expandable nail 1 and the expander inserts 3, 5, 7
- are made of a titanium alloy and all the other
- 34 components of the apparatus are made of stainless steel
- 35 except the end plates 25, 21 which are made of mild

1

steel.

WO 94/12112 PCT/GB93/02390

11

2 Further embodiments of the present invention will now be described. 4 5 Fig 4a-e shows an alternative cross-sectional 7 configuration for an intramedullary nail and a series 8 of expander inserts to that shown in Fig 3a-f. 9 10 The cross section of the nail of this embodiment is not 11 circular but is configured so as to slidingly engage a 12 shaped portion of the expander insert, as the expander 13 is inserted into or withdrawn from the nail. 14 15 This alternative configuration gives greater stability 16 of position of the expander insert as it moves relative 17 to the nail, and also helps prevent rotation of the 18 nail with respect to the bone. 19 20 Fig 4f shows a slightly differently shaped, but 21 functionally similar intramedullary nail to those shown 22 in Figs 4a-e. 23 24 Figs 6a,b, 7a, b and 8a, b show side views (6a, 7a, 8a) 25 and front views (6b, 7b, 8b) of alternative expander 26 insertion/extraction devices 600, 700, 800 to those 27 shown in Fig 5a,b. 28 29 Each of the devices has a similar structure to the 30 devices of Figs 5a, b except that a screw jack 31 mechanism is used in place of the ratchet mechanism and 32 that power can be provided either manually by turning a 33 handle 601 or by an electric motor which is supplied by a lead 704, 804 or possibly battery operated (not 34 35 shown). Other methods of providing a force, such as

1 hydraulics could also be used.

2

Fig 6b shows an expander insertion/extraction device 3 600 having two handles 601, 602 and a threaded rod 603 which, when rotated, acts as a screw jack mechanism 5 providing a controllable force for the insertion of an 6 expander into, or extraction of an expander from, an 7 intramedullary nail. The device includes a rear end 8 plate 621 and a front end plate 609 which are connected 9 10 by tie rods 620, 623. The rear of the threaded rod 603 11 passes through a threaded aperture in the rear end 12 plate 621 and attaches rigidly to a handle 601 such 13 that rotation of the handle 601 also rotates the threaded rod 603 and controls its movement through the 14 15 aperture in the end plate 621 thus controlling the 16 length of the threaded rod which extends from the rear

end plate 621 towards the front end plate 609.

17 18 19

20

21

22

23

24

25

The threaded rod 603, at its end nearest the front end plate 609, engages a thrust plate 608 which moves along the tie rods 620,623, that is in a substantially straight line between the front end plate 609 and the rear end plate 621. The thrust plate 608 engages a push/pull member 624 which passes through an aperture in the front end plate 609 and attaches to the expander which is to be forced.

262728

29

30

Thus in use, rotation of the handle 601, which can be performed manually, results in a force, in an axial direction according to the direction of the rotation, on the expander.

3132

The expander insertion/extraction devices shown in figs 7a and 8a, 700, 800 respectively, work in a similar manner to the device 600 and will thus not be described

1 in detail. Corresponding parts of each of the three 2 devices are denoted by three figure numerals in which 3 the first digit denotes the device and the latter two 4 digits are common. 5 6 Two of the devices 700,800 are shown as being operated 7 by an electric motor supplied by a flex 704,804. 8 the handles 701,801 do not rotate and the screw 9 threaded rod does not attach to the handle 701,801 but 10 is driven by the electric motor via transmission 11 components in the housing 770,870. 12 13 The two electrically driven devices 700,800 are 14 operated by use of buttons 750,851,852 located on a 15 handle of the device. One of the devices 800 is shown 16 as having two buttons 851,852 one corresponding to each 17 direction of rotation of the threaded rod. 18 19 The front views of the devices show a vertical member 20 690, 790, 890. This member is for use in attaching the 21 push/pull member to the expander. As an alternative to 22 the screw portion 3 of the expander 40, an expander 23 could be configured with an aperture adjacent to one 24 end of said member as shown in Figure 12. 25 member 690,790,890 passes through the aperture thus 26 securely engaging the expander. 27 28 In Figs. 6a, 7a and 8a the nail extends a distance 29 outside the bone while it is being expanded. 30 portion of the nail extending from the bone has 31 benefits over inserting it so that it is entirely 32 contained within the bone, in that it prevents or 33 reduces the growth of callus over the nail and also 34 facilitates subsequent removal of the nail from the

35

bone.

Fig 10 a,b shows an alternative embodiment of an 1 expandable intramedullary nail to that shown in Fig 9 2 The cross sectional shape, shown in Fig 10b, is 3 4 not round but is shaped to help prevent rotation of the nail relative to the bone and also to help guide a 5 suitably shaped expander into or out of the nail. 6 7 can also be seen from Fig 10a that the break in cross section 1030 is flared, widening towards the end where 8 an expander would be inserted. 9 This facilitates the 10 initial insertion of the expander. The end which would 11 be foremost when the nail is inserted into a bone is shaped without sharp corners in order to prevent 12 13 catching on the inside of the bone and facilitates 14 insertion of the nail into the medullary cavity. 15 16 Fig 12a shows a side view and Fig 12b shows an end view 17 of the type of expander illustrated in Fig. 4. 18 aperture 1201 is provided as a means of attachment to an insertion or extraction device as described above. 19 20 21 Figs 13a, b show a further embodiment of an expander 22 for an expanding intramedullary nail comprising two 23 longitudinal sections 1305, 1306 which have teeth with 24 corresponding angled surfaces. The angled surfaces of 25 the teeth are arranged such that a force applied to a 26 first end 1309 of one of the longitudinal sections 27 1302, causing it to move in an axial direction relative 28 to the other longitudinal section 1301, results in 29 angled surfaces of the teeth 1303,1304 moving against 30 each other and gradually disconnecting as shown in Fig 31 13b, causing corresponding motion of the sides of the 32 expander 1305,1306, away from each other. 33

In use the expander insert is inserted in its unexpanded form into the intramedullary nail (not

shown). Apparatus (not shown) would be provided to 1 force the longitudinal sections 1301, 1302 to move 2 axially relative to each other. Such apparatus might 3 comprise a device such as shown in any one of Figs 5-8 5 with the addition of an attachment means to prevent movement of the longitudinal section of the expander 6 7 insert which is to remain stationary. Thus the 8 longitudinal sections would be forced to move relative 9 to each other thereby causing the expansion of the 10 expander insert as detailed above. 11 The expander insert, on expansion, forces the 12 13 intramedullary nail to expand with the break in cross-14 section widening to accommodate the expander insert. 15 16 Use of an expander of this type requires a locking 17 mechanism either on the expander itself, or on the 18 nail. Such a locking mechanism would be necessary to 19 maintain the nail in its expanded state. A locking 20 mechanism on the expander would require the expander to be left in the nail for as long as the expanded state 21 22 is required. If the locking mechanism were on the nail 23 the expander could be removed leaving the lock expanded 24 nail in situ in the patient's bone. 25 26 Fig 14 shows a preferred embodiment of an expander 27 insertion/extraction device 1400 similar to that shown 28 in Fig 6. 29 30 In this embodiment there is a threaded rod 1403 which is hollow and contains a solid rod 1404 which extends 31 through a thrust plate 1408. The solid rod 1404 is 32 attached to a push/pull member 1461 by a locking device 33 34 1478 which provides two pins 1479, 1480 one of which 35 passes through the solid rod 1404 and of one which

16

passes through the push/pull member 1461. The solid rod 1404 is secured to the thrust plate 1408 by a pin.

3 This arrangement gives secure connection of the

4 threaded rod 1403 to the thrust plate 1408 and

5 push/pull member 1461/1462 during both insertion and

6 extraction procedures.

7

8 The expander insertion/extraction device also includes

9 two pins 1439, which, in use, engage apertures in an

intramedullary nail 1401 in order to secure the device

11 to the nail. The pins 1439 are attached to members

12 1440 which engage the outside of the nail 1401, thus

differing from the arrangement shown in Figs 1a, 2a and

14 greatly facilitating the insertion of the pins 1439

into the apertures. The pins 1439 are secured in the

apertures by a circlip 1474 which forces the members

17 1440 against the outside of the nail 1.

18

19 Push and pull members 1461,1462 for use with the device

of Fig 14 are shown in Fig 15a,b and 16a,b

21 respectively.

22

20

23 The push member 1461 consists of a rod which has one

24 end portion configured for attachment to the solid rod

25 1404 via the locking device 1478 and the other end

26 portion configured for engaging, and applying a pushing

27 force to, an expander.

28

29 A pull member 1462 consists of a rod similar to the

30 push member 1461 except that the end portion which

31 engages an expander is configured for the application

32 of a pulling force.

33

The portion of the push member 1461 or pull member 1462

35 configured to be attached to the solid rod 1404 of the

17

insertion/extraction device 1400 comprises a flattened 1 2 part with an aperture. The aperture, in use, engages the pin 1479 which is provided by the locking device 3 1478. 4 5 The portion of the push member 1461 configured to 6 7 engage the expander comprises a slot into which a 8 portion of the expander fits. 9 10 The portion of the pull member 1462 configured to 11 engage the expander comprises a hook shaped member 12 which, in use, passes through the aperture 1201 of an 13 expander such as that shown in Fig. 12a. 14 15 Fig. 17 shows a cross section of an intramedullary nail 16 according to the present invention which incorporates a 17 locking device such that it could be suitable for use 18 with the expander insert shown in Figs 13a,b. 19 20 The nail comprises a cylindrical tube 1700 with a break 21 in cross section 1704 and a pair of members 1705,1706 22 extending from either side of the break in cross 23 section into the interior of the cylindrical tube 1700. 24 The members 1705,1706 are curved or bent, and 25 configured such that expansion of the tube by increasing the size of the break in cross section 26 causes at least some portions of the members to move 27 28 longitudinally against each other. The portions of the 29 members which move against each other are each equipped 30 with teeth with inclined surfaces configured such that 31 motion of the members 1705,1706 against each other in 32 the direction that corresponds to expansion of the tube 33 1100 is possible, but motion in the opposite direction 34 is prevented for as long as the teeth 1703 on the two 35 members 1705,1706 engage each other.

18

The two members 1705,1706 include portions 1707,1708 spaced apart from each other. These spaced portions

3 1707,1708 are parallel to and proximate to the toothed

4 portions.

5

6 The two members 1705,1706 are configured such that the

7 toothed portions are aligned substantially orthogonal

8 to a radius of the cylindrical tube 1700 that crosses

9 the break in cross section 1704. The members 1705,1706

10 are also configured so as to allow an expander 1701 of

11 the type shown in Fig 13 to be inserted into the

cylindrical tube 1700 and occupy a diameter of the tube

13 substantially parallel to the toothed portions of the

14 members 1705,1706.

15

17

19

In use the tube 1700 is inserted in its unexpanded form

into the medullary cavity of the bone to be secured.

18 An expander 1701 of the type shown in Figs 13a,b and

described above is then inserted into the hollow

20 portion of the tube 1700.

21

22 An operating means (not shown) is then used to operate

23 the expander 1701 and thus expand the tube by the

desired amount. As the tube 1700 expands, the teeth

25 1703 on the members 1705,1706 slide over each other.

26

27 When the desired expansion of the tube has been

obtained the expander may be returned to its original

29 configuration (as shown in Fig 13a) and the nail

30 remains expanded, unable to return to is expanded state

31 because of the engaging teeth 1703 on the members

32 1705,1706. The operating means and expander 1701 can

33 thus be removed from the proximity of the nail leaving

34 the nail in its expanded form.

When the expansion of the nail is to be reversed an 1 2 elongate member can be inserted into a space, 1702, formed by the spaced apart portions 1707,1708 of the 3 4 members 1705,1706. Insertion of the elongate member, 5 which is dimensioned to be slightly larger than the natural distance between the spaced apart portions 6 7 1707,1708 of the members 1705,1706, forces the spaced 8 apart portions 1707,1708 away from each other thus 9 disengaging the teeth and allowing the tube 1700 to revert to its unexpended form. 10 12 Improvements and modifications may be incorporated

11

13 without departing from the scope of the invention.

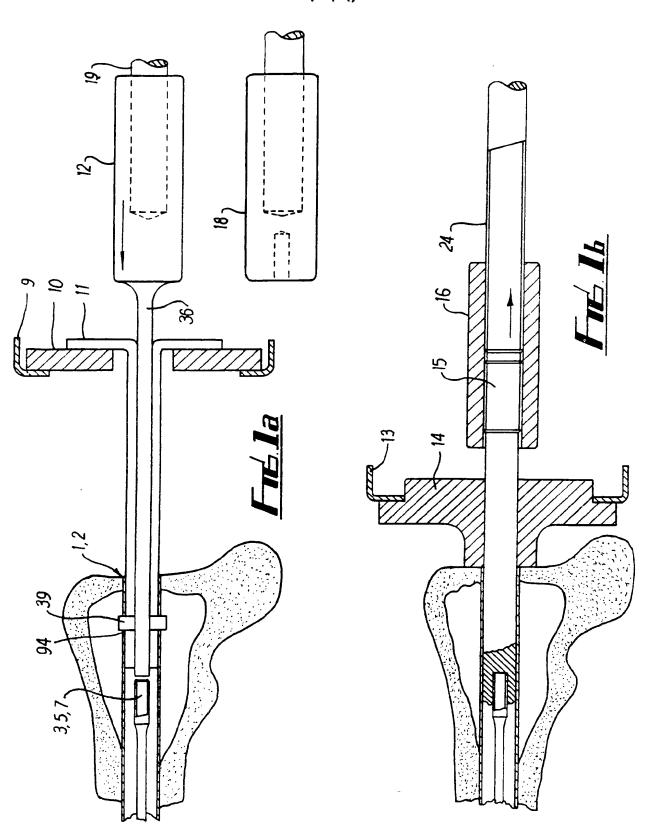
1	<u>CLA</u>	<u>IMS</u>
2		
3	1	Apparatus for pinning one or more bone elements
4		comprising an intramedullary nail being
5		selectively cross-sectionally expandable along
6		substantially the entire length of the nail, an
7		expander for said nail, and operating means for
8		operating said nail in conjunction with said
9		expander.
10		
11	2	An intramedullary nail being selectively cross
12		sectionally expandable along substantially the
13		entire length of the nail.
14		
15	3	A nail as claimed in Claim 2 wherein the nail is
16		hollow and elongate.
17		
18	4	A nail as claimed in either of Claims 2 or 3
19		wherein the nail is expandable in situ within a
20		bone.
21		
22	5	A nail as claimed in any one of Claims 2 to 4,
23		wherein the nail has a broken cross section
24		throughout substantially its entire length and is
25		expandable by enlarging the break in the cross
26		section.
27		
28	6	A nail as claimed in any one of Claims 3 to 5,
29		wherein the nail is configured so as to be
30		enlargeable by an expander in the form of an
31		elongate insert, inserted into the hollow portion
32		of the nail.
33		
34	7	A nail as claimed in Claim 5 wherein the break in
35		cross section is configured so as to accommodate

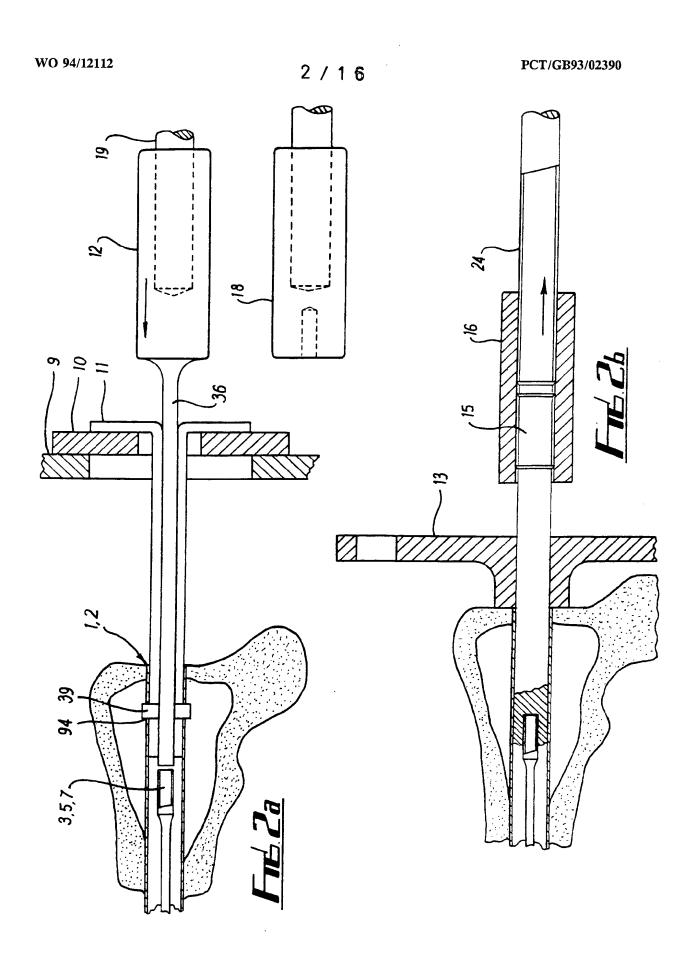
WO 94/12112

PCT/GB93/02390

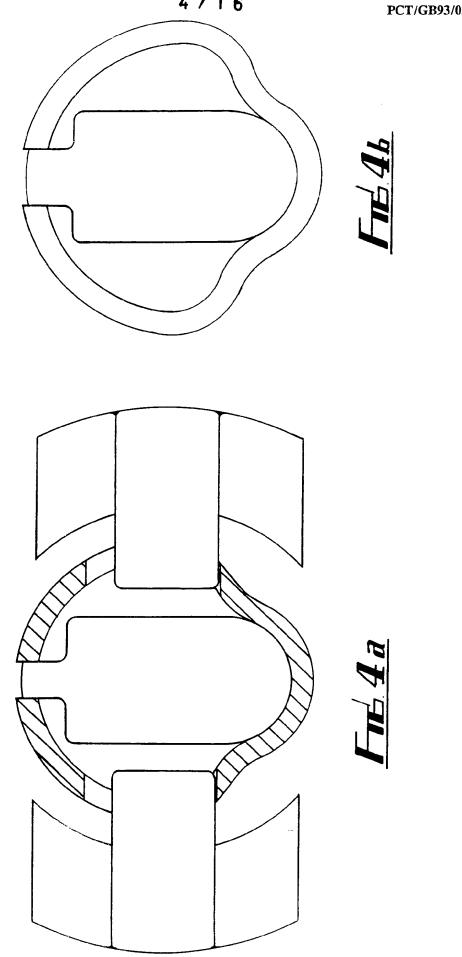
1		the insertion of an expander or successive
2		insertion of a plurality of expanders, each
3		expander being in the form of an elongate member.
4		
5	8	An expander for use in the apparatus of Claim 1,
6		comprising a first portion for engagement of an
7		intramedullary nail and a second portion
8		configured to be engaged by an operating means for
9		said nail and expander.
10		
11	9	An expander as claimed in Claim 8 wherein the
12		expander is in the form of an elongate insert for
13		insertion into a hollow portion of an expandable
14		intramedullary nail.
15		
16	10	An expander as claimed in Claim 9 wherein the
17		elongate insert comprises a plurality of elongate
18		members having cooperating surfaces and configured
19		such that relative axial movement of the members
20		results in their non-cooperating surfaces being
21		forced away from each other effecting an increase
22		in the total cross section of the insert.
23		
24	11	An expander as claimed in Claim 8 or 9 wherein the
25		first portion is insertable into the break in
26		cross section of the nail of Claim 5, and is
27		adapted to prise open the break by an amount
28		determined by the size and shape of the expander,
29		and the second portion is configured so to be
30		engageable by an expander insertion/extraction
31		means.
32		
33	12	An expander as claimed in Claim 11 having a shaped
34		portion configured to engage a portion of the
35		inside surface of an intramedullary nail

configured to have a complementary shape. 1 2 3 Operating means for use with an intramedullary 13 4 nail, said nail being expandable along substantially its entire length, comprising 5 engaging means which engages the nail and means 6 7 for applying or releasing a force to or from said nail. 8 9 Operating means as claimed in Claim 13, being 10 14 11 adapted for the insertion and/or extraction of an expander, comprising a push and/or pull member 12 13 adapted to engage the expander, forcing means 14 which provides force to the push and/or pull 15 member and nail engaging means, which in use, 16 braces the nail against the operating means. 17 18 15 Operating means as claimed in Claim 13 or 14 19 wherein the forcing means comprises a screw jack 20 mechanism, ratchet mechanism or other 21 substantially non-percussive mechanism. 22

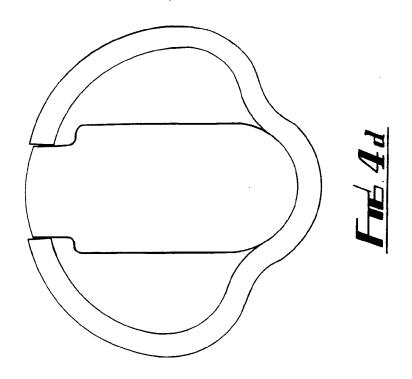


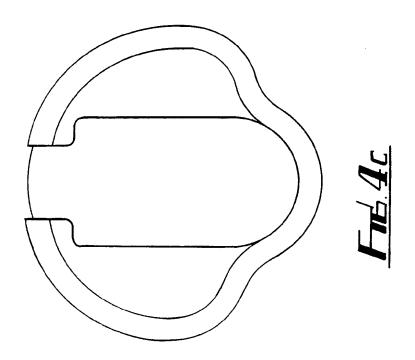


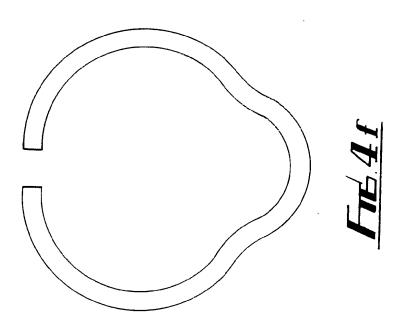
SUBSTITUTE SHEET

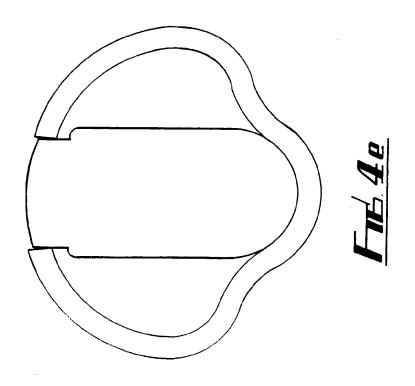


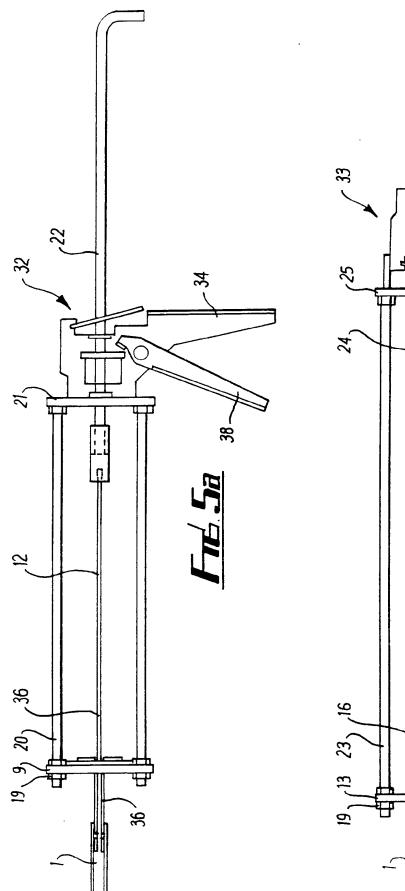
SUBSTITUTE SHFFT

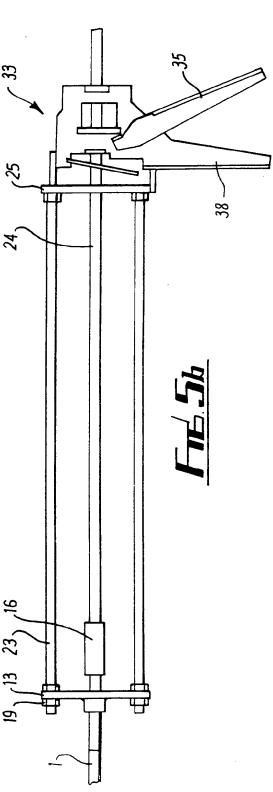






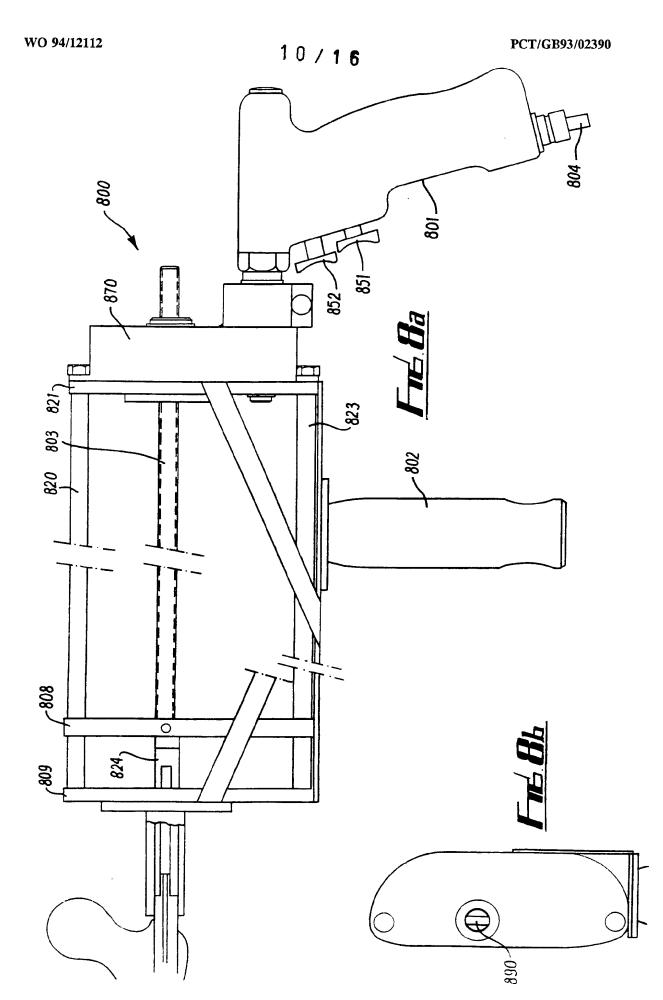




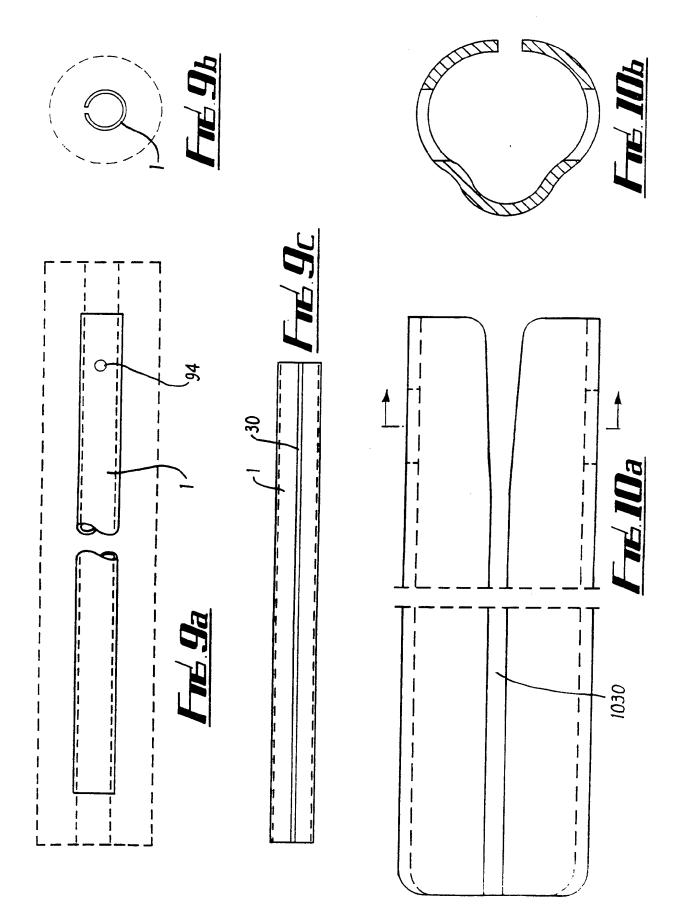


SUBSTITUTE SHEET

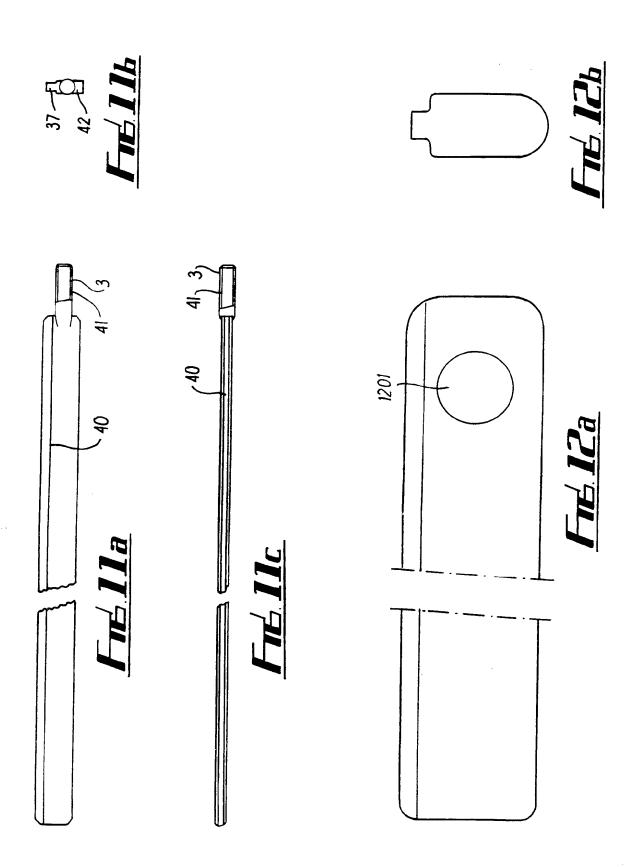
SUBSTITUTE SHEET

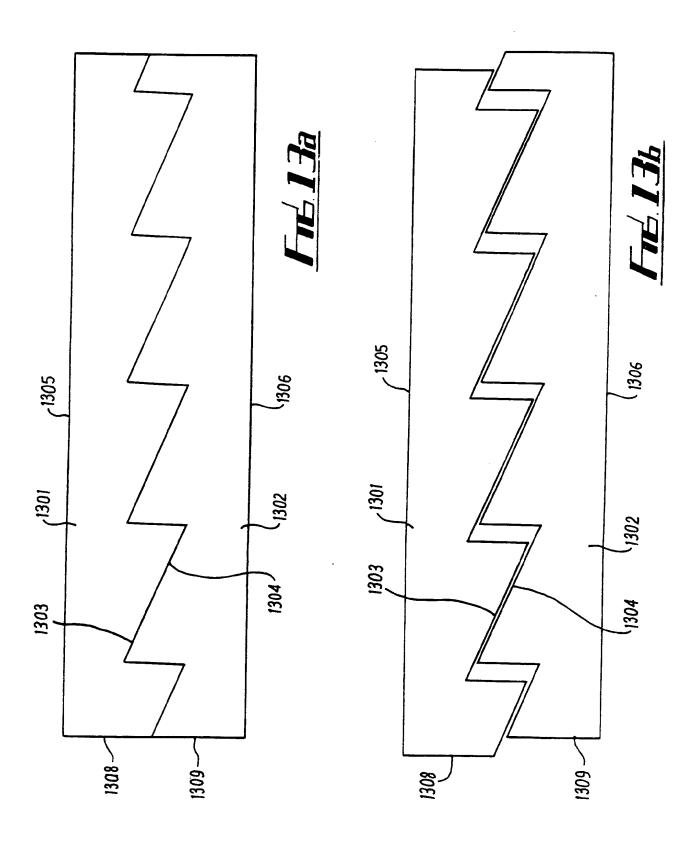


SUBSTITUTE SHEET



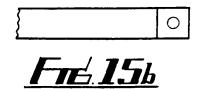
SUBSTITUTE SHEET

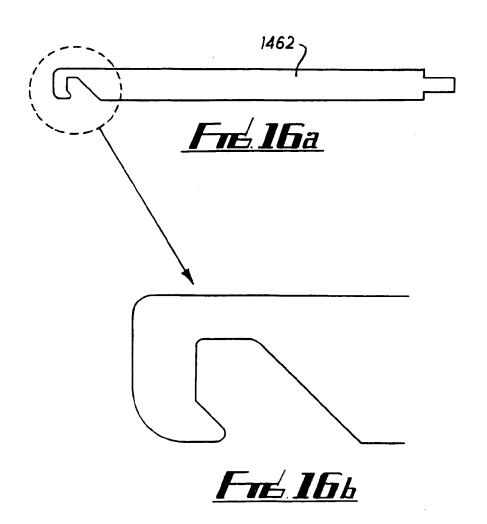


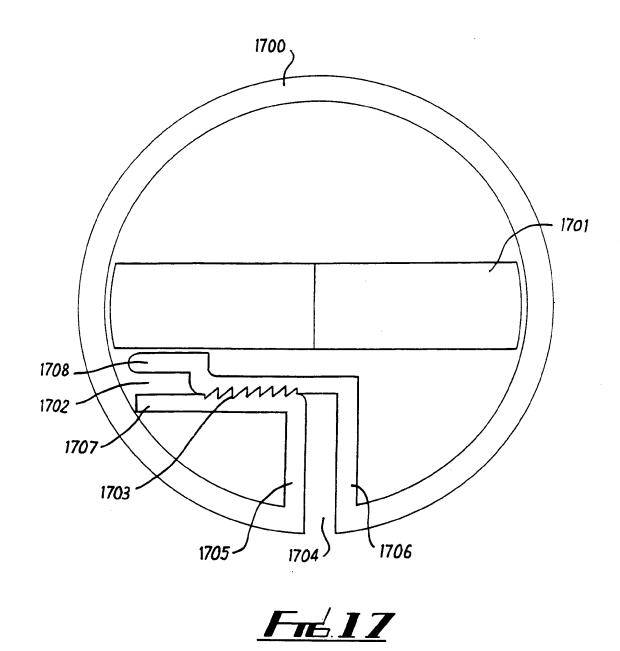


SUBSTITUTE SHEET









SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

Inter. ...al Application No PCT/GB 93/02390

A. CLASS IPC 5	MATTER A61B17/58		
	to International Patent Classification (IPC) or to both national classi	fication and IPC	
	S SEARCHED documentation searched (classification system followed by classification)	tion symbols)	
IPC 5	A61B A61F	·	
Documenta	tion searched other than minimum documentation to the extent that	such documents are included in the fields s	earched
Electronic	data base consulted during the international search (name of data bas	se and, where practical, search terms used)	
	· · · · · · · · · · · · · · · · · · ·		
			•
C. DOCUM	MENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the re-	elevant passages	Relevant to claim No.
Х	DE,C,745 873 (POHL) 10 August 195	53	1-9, 11-13,15
	see the whole document		
A	US,A,5 116 335 (HANNON) 26 May 19 see claim 1; figures	992	10
A	DE,U,84 00 640 (MECRON) 20 June 3 see figures 3,4	1985	14
A	US,A,4 854 312 (RAFTOPOULUS) 8 Au	ugust 1989	
A	WO,A,88 01492 (OFFICE MEDICO CHIE INTERNATIONAL) 10 March 1988	RURGICAL	
A	US,A,4 531 517 (FORTE) 30 July 19	985	
Fur	ther documents are listed in the continuation of box C.	X Patent family members are listed	in annex.
"A" docum	ategories of cited documents: nent defining the general state of the art which is not dered to be of particular relevance	"T" later document published after the int or priority date and not in conflict we cited to understand the principle or the	th the application but
	document but published on or after the international	 'X' document of particular relevance; the cannot be considered novel or canno 	t be considered to
which	nent which may throw doubts on priority claim(s) or n is cited to establish the publication date of another on or other special reason (as specified)	involve an inventive step when the do 'Y' document of particular relevance; the cannot be considered to involve an in	claimed invention
"O" docum other	nent referring to an oral disclosure, use, exhibition or means	document is combined with one or ments, such combination being obvious the art.	ore other such docu-
	nent published prior to the international filing date but than the priority date claimed	'&' document member of the same paten	
Date of the	e actual completion of the international search	Date of mailing of the international se	25, 03 94
	10 March 1994		
Name and	mailing address of the ISA European Patent Office, P.B. 5818 Patentiaan 2	Authorized officer	
	NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Steenbakker, J	

, 1

INTERNATIONAL SEARCH REPORT

information on patent family members

Inte onal Application No PCT/GB 93/02390

Patent document cited in search report	Publication date	Patent family member(s)		Publication date	
DE-C-745873		NONE			
US-A-5116335	26-05-92	NONE			
DE-U-8400640	20-06-85	NONE			
US-A-4854312	08-08-89	NONE			
WO-A-8801492	10-03-88	FR-A- EP-A- US-A-	2606997 0278963 4911722	27-05-88 24-08-88 27-03-90	
US-A-4531517	30-07-85	NONE			

Form PCT/ISA/210 (patent family annex) (July 1992)